PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 22037-4PC	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US06/34130	International filing date *(day/month/year)* 29 August 2006 (29.08.2006)	Priority date *(day/month/year)* 02 November 2005 (02.11.2005)
International Patent Classification (IPC) or national classification and IPC IPC: **A61F 2/06**(2006.01) USPC: 623/1.11		
Applicant CARDIOMIND, INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01 June 2007 (01.06.2007)	14 October 2008 (14.10.2008)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Tom Dunn Telephone No. 571 272-1700

Form PCT/IPEA/409 (cover sheet)(April 2007)

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on:
   - ☒ the international application in the language in which it was filed.
   - ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
     - ☐ international search (under Rules 12.3(a) and 23.1(b))
     - ☐ publication of the international application (under Rule 12.4(a))
     - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
   - ☒ the international application as originally filed/furnished
   - ☒ the description:
     pages 1-40 as originally filed/furnished
     pages* NONE received by this Authority on ____
     pages* NONE received by this Authority on ____
   - ☒ the claims:
     pages 41-44 as originally filed/furnished
     pages* NONE as amended (together with any statement) under Article 19
     pages* NONE received by this Authority on ____
     pages* NONE received by this Authority on ____
   - ☒ the drawings:
     pages 1-23 as originally filed/furnished
     pages* NONE received by this Authority on ____
     pages* NONE received by this Authority on ____
   - ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages ____
   - ☐ the claims, Nos. ____
   - ☐ the drawings, sheets/figs ____
   - ☐ the sequence listing (*specify*): ____
   - ☐ any table(s) related to the sequence listing (*specify*): ____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages ____
   - ☐ the claims, Nos. ____
   - ☐ the drawings, sheets/figs ____
   - ☐ the sequence listing (*specify*): ____
   - ☐ any table(s) related to the sequence listing (*specify*): ____

5. ☐ This report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2(e)).

** If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:

   ☐ restricted the claims.

   ☒ paid additional fees.

   ☐ paid additional fees under protest, and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ neither restricted the claims nor paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

   ☐ complied with.

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: claims 1-2 are directed to a power supply for an implant delivery system.

Group II: claims 3-38 are directed to a stent delivery system.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding technical features for the following reasons:

Groups II does not include the inventive concept of a power supply.

Groups I does not include the inventive concept of a stent delievery system.

None of these technical features are common to the other groups, nor do they correspond to a special technical feature in the other groups. Therefore, unity of invention is lacking.

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☒ all parts

   ☐ the parts relating to claims Nos. _____

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 6, 9, 11, 13, 16-29, 31-34	YES
	Claims 1-5, 7, 8, 10, 12, 14, 15, 30, 35-38	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-38	NO
Industrial Applicability (IA)	Claims 1-38	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V. 2. Citations and Explanations:
Claims 1 and 2 lack novelty under PCT Article 33(2) as being anticipated by US 5,643,254 A to Scheldrup et al. (hereinafter 'Scheldrup').

As per claim 1, Scheldrup describes a power supply for an implant delivery system employing at least one electrolytically erodable element (electrolytic detachment of an embolic device, (Abstract)), the improvement comprising: adaptation of the power supply to provide an AC voltage profile with a peak-to-peak configuration of at least about 5V (the amplifier delivers constant DC current with AC superposition, (col 7, ln 14-16); A positive electric current ... at 0.1-6 volts, (col 5, ln 28-30)) and a DC voltage signal of at least about 1V (A DC current of between ... 0.1 to 6 volts, (col 5, ln 63-65)).

As per claim 2, Scheldrup describes method of implant delivery, the method comprising: introducing an implant delivery system in an electrolytic fluid (Electrolytic separation of a device from a guidewire may be facilitated by means of the assembly 100 shown in FIG. 2, (col 3, ln 55-58)); and applying electrical power to an electrolytically erodable member, the power AC voltage profile with a peak-to-peak configuration of at least about 5V (the amplifier delivers constant DC current with AC superposition, (col 7, ln 14-16); A positive electric current ... at 0.1-6 volts, (col 5, ln 28-30)), and a DC voltage signal of at least about 1V (A DC current of between ... 0.1 to 6 volts, (col 5, ln 63-65)).

Claims 3-5 and 7 lack novelty under PCT Article 33(2) as being anticipated by US 2005/0220836 A1 to Falotico et al. (hereinafter 'Falotico').

As per claim 3, Falotico describes a method of loading a self-expanding stent (stent 100 ... may be made self-expanding, para[0128]) onto a delivery guide (insertion in a blood vessel or other tissue by insertion means, wherein the insertion means include a suitable catheter, or flexible rod, para[0128]), the method comprising: holding the stent compressed to a reduced diameter configuration (stent

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100 has been formed it may be compressed, para[0128]) in at least one sleeve (the stent to include one or more ... sleeves, para[0396]; engaging the stent with the delivery guide (a suitable catheter, or flexible rod, para[0128]); and twisting the stent while in the sleeve (twisting it into a braided configuration, para[0128]).

As per claim 4, Falotico describes the method of claim 3, further comprising compressing the stent before loading the stent (after the stent 100 has been formed it may be compressed so as to occupy a space sufficiently small as to permit its insertion in a blood vessel or other tissue by insertion means, para[0128]) into the at least one sleeve (the stent to include one or more ... sleeves, para[0396].

As per claim 5, Falotico describes the method of claim 3, wherein a plurality of sleeves hold the stent (the stent to include ... sleeves ... for positioning a system component, para[0396]).

As per claim 7, Falotico describes the method of claim 3, further comprising removing the at least one sleeve from the stent (delivery of self-expanding stents which typically require the retraction of a delivery sheath, para[0439]).

Claim 6 lacks an inventive step under PCT Article 33(3) as being obvious over Falotico. Faltico describes a method of claim 5 wherein the stent is twisted (twisting it into a braided configuration, para[0128]) and has a plurality of sleeves (the stent to include one or more ... sleeves, para[0396]). It would have been obvious to one skilled in the art to twist the stent by rotating the sleeves which cover them.

Claims 8, 10, 12, 14, 15, 30 and 35-38 lack novelty under PCT Article 33(2) as being anticipated by US 6,168,618 B1 (Frantzen).

As per claim 8, Frantzen describes a stent delivery system comprising: a delivery guide body having a distal portion (distal end 22 of catheter 21, (col 3, ln 32-46) and at least one elongate member including an electrolytically erodable section (binding straps 30 to erode via electrolytic action, (col 3, ln 10-15)); a stent comprising a near end, a far end and a structure extending therebetween (stent 10, FIG. 2, (col 3, ln 15-22)), at least one of the near and far end of the stent held in contact with the elongate body; wherein release of the erodable section initiates stent release (straps that causes them to erode, thus permitting the stent to partially or fully expand (col 3, ln 5-8)).

As per claim 10, Frantzen describes the system of claim 8, wherein at least one elongate member passes through the near or far end of the stent (guide wire 40, FIG. 2).

As per claim 12 Frantzen describes the system of system of claim 8, wherein each elongate member defines a loop of material (Binding straps may be formed from continuous loops of material, (col 4, ln 10-12)).

As per claim 14, Frantzen describes the system of claim 8, further comprising a slidably actuable tubular restraint over at least a portion of the stent (present invention may be used with or without a retractable exterior sheath, (col 7, ln 6-8)).

As per claim 15, Frantzen describes the system of claim 14, wherein only one of the near and far ends of the stent is held by an elongate member (constrained in a contracted delivery state by one or more metal straps, (col 2, ln 11-13)).

As per claim 30, Frantzen describes the system of claim 8, further comprising a sleeve restraining the stent in a compressed state (invention may be used with or without a retractable exterior sheath, (col 7, ln 6-10)) wherein the sleeve is releasably secured by the erodable section (binding straps 30 to erode via electrolytic action, (col 3, ln 10-15).

As per claim 35, Frantzen describes the system of claim 8, wherein any erodable section releases the stent directly (straps that causes them to erode, thus permitting the stent to partially or fully expand (col 3, ln 5-8)).

As per claim 36, Frantzen describes the system of claim 8, wherein any erodable section releases the stent indirectly (invention may be used with or without a retractable exterior sheath, (col 7, ln 6-10) and binding straps 30 to erode via electrolytic action, (col 3, ln 10-15) which would require both actions to release the stent.

As per claim 37, Frantzen describes the system of claim 8, wherein any elongate member maintains the stent in a rotationally stable configuration for delivery (see FIG. 1A and FIG. 1B, a stent is constrained in a contracted delivery state with binding straps, (col 2, ln 8-10)).

As per claim 38, Frantzen describes the system of claim 37, wherein any elongate member, alone, maintains the stent in a rotationally stable configuration for delivery (a stent is constrained in a contracted delivery state with binding straps, (col 2, ln 8-10)).

Claims 9 and 16-21 lack an inventive step under PCT Article 33(3) as being obvious over Frantzen in view of Falotico.

As per claim 9, Frantzen describes the system of claim 8 wherein the stent is in a rolled configuration (see FIG. 1), but fails to describe a twisted configuration. However, Falotico describes a self expanding stent (stent 100 ... may be made self-expanding, para[0128]) in a twisted configuration (twisting it into a braided configuration, para[0128]). It would have been obvious to one skilled in the art to use a

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twisted configuration for the compressed state as described by Falotico on the system described by Frantzen because they bothdescribe deployment of self-expanding stents.

As per claim 16, Frantzen describes the system of claim 8, wherein the stent comprises at least one of a near and far mating portion at the near and far ends (locking teeth 12 along its innermost edge 14, (col 3, ln 25-27)), but fails to mention locking them to the guide instead of itself. However, Falotico describes a self expanding stent (stent 100 ... may be made self-expanding, para[0128]) with mating portions in the guide member (the stent to include one or more holes, apertures, points ... for engaging, preferably matingly engaging, para[0396]). It would have been obvious to one skilled in the art to mate the stent to the guide wire as taught by Falotico instead of itself as taught by Frantzen because they both describe mating of self expanding stents.

As per claim 17, Frantzen describes the system of claim 16, wherein at least one elongate member is wrapped to at least partially cover each mating portion (a greater or lesser number of binding straps may be used depending upon the length of the stent and other factors particular to the application, (col 7, ln 12-15)).

As per claim 18, Falotico describes the system wherein at least some of the mating portions and seats provide a keyed interface (the stent to include one or more holes, apertures, points, slits, para[0396]).

As per claim 19 Frantzen describes the system of claim 17, wherein at least some of the mating portions and seats provide a slide-out interface (see FIG. 1A and 1B).

As per claim 20, Falotico describes the system, wherein the stent is in a twisted configuration in contact with the delivery guide body (twisting it into a braided configuration, para[0128])).

As per claim 21, Frantzen describes the system wherein each seat receives a mating portion (locking teeth 12 along its innermost edge 14, (col 3, ln 25-27)), and wherein at least one seat is rotatable upon release of an electrolytically erodible section (see FIG. 1A and FIG. 1B).

Claims 11 and 34 lack an inventive step under PCT Article 33(3) as being obvious over Frantzen in view of US 6,425,914 B1 to Wallace et al. (hereinafter 'Wallace').

As per claim 11, Frantzen describes the system of claim 8, but fails to describe the erodable section being away from the stent. However, Wallace describes a stent wherein the electrically eroding joint (196) is away from the stent (192) (FIG. 7, col 7, ln 8-10). It would have been obvious to one skilled in the art to place the erodable segments away from the stent as described by Wallace on the device of Frantzen because both describe stents deployed by electrically eroded joints.

As per claim 34, Frantzen describes the system of claim 8, but fails to describe the erodable section being away from the stent. However, Wallace describes a stent wherein the electrically eroding joint (196) is away from the stent (192) (FIG. 7, col 7, ln 8-10). It would have been obvious to one skilled in the art to place the erodable segments away from the stent as described by Wallace on the device of Frantzen because both describe stents deployed by electrically eroded joints.

Claims 13, 26-29 and 31-33 lack an inventive step under PCT Article 33(3) as being obvious over Frantzen in view of US 4,553,545 A to Maass et al. (hereinafter 'Maass').

As per claim 13, Frantzen describes the system of claim 8, but fails to describe capped ends. However, Maass describes a self expanding stent with capped ends (end sections 40, 41, see FIG. 17). It would have been obvious to one skilled in the art to cap the ends of the stent as described by Maass on the device described by Frantzen because they bothdescribe self expanding stents.

As per claim 26, Frantzen describes the system of claim 8, but fails to describe releasing the stent by relative motion of the guide and the stent. However, Maass describes a self expanding stent (an expanding, self-fixating applicance for blood vessels, (col 1, ln 14-16)) wherein one end of the stent is released by relative sliding motion between the stent and the delivery guide body (metal wire 77 is removed whereupon spring 21 is brought to expand (col 12, ln 4-6)). It would have been obvious to one skilled in the art to employ relative motion between a guide member and the stent as described by Maass in the stent described by Frantzen because both describe deployment designs for self extracting stents.

As per claim 27, in claim 26 Frantzen described a stent release system wherein an electrically eroding member releases the compressed stent, but fails describe sliding release. However, in claim 26 Maass describes a self expanding stent with a sliding release. It would have been obvious to one skilled in the art to implement an electrically eroding stent release as described by Frantzen in place of the wire release described by Maass because both describe release mechanisms for self expanding stents.

As per claim 28, Maass describes the stent delivery system of claim 26, wherein the sliding release occurs as result of advancing or withdrawing the delivery guide by a user (metal wire 77 is removed whereupon spring 21 is brought to expand (col 12, ln 4-6)).

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As per claim 29, Maass describes the system of claim 28, further comprising a catheter in which the delivery guide is received, an end of the catheter adapted to abut the near end of the stent upon release of the far end of the stent (The other end 92 of spring 90 may then ... be held ... in connection to end section 41, (col 14, ln 40-46)).

As per claim 31, Frantzen describes the system of claim 30, but fails to describe a spring positioned to actuate the sleeve. However, Maass describes a self expanding stent (an expanding, self-fixating applicance for blood vessels, (col 1, ln 14-16)) with a spring positioned to actuate the sleeve (By turning the shaft and/or the sleeve relative to each other the diameter of the spring can hereby be decreased or increased, (col 2, ln 39-44)). It would have been obvious to one skilled in the art to implement a spring and sleeve system as described by Maass on the device describe by Frantzen as an alternate deployment means because both describe deployment of self extracting stents.

As per claim 32, Maass describes the system of claim 31, wherein the spring is a coil spring having a compressed, extended state and an expanded, retracted state (see FIG. 8 and 9).

As per claim 33, Frantzen describes the system of claim 32, wherein retraction of the sleeve frees the stent to expand from the compressed state (are constrained in a contracted delivery state by a locking wire or exterior sheath (col 1, ln 38-40); invention may be used with or without a retractable exterior sheath, (col 7, ln 6-10)).

Claims 22 and 23 lack an inventive step under PCT Article 33(3) as being obvious over Frantzen in view of US 2004/0260383 A1 to Stelter et al. (hereinafter 'Stelter').

As per claim 22, Frantzen describes the system of claim 8, wherein engagement of the at least one mating portion on one of the near and far ends of the stent is released by release of an electrolytically erodable member (straps that causes them to erode, thus permitting the stent to partially or fully expand (col 3, ln 5-8)), but fails to describe the engagement of the opposite end during the same process. However, Stelter describes a self expanding stent with a second mating portion that becomes engaged after the first is released (a two-step trigger mechanism that keeps the tube restrained to a smaller diameter than the lumen dimension, para[0033]). It would have been obvious to one skilled in the art to add a second step on the trigger as described by Stelter on the stent described by Frantzen because they both describe the release mechanisms of self expanding stents.

As per claim 23, Frantzen describes the system of claim 22, wherein movement of a floating cap releases the other end of the stent (present invention may be used with or without a retractable exterior sheath, (col 7, ln 6-8)).

Claims 24 and 25 lack an inventive step under PCT Article 33(3) as being obvious over Frantzen in view of Stelter, in further view of Maass.

As per claim 24, Frantzen describes the system of claim 22, wherein a stent is released upon the release of the electrically erodable member (straps that causes them to erode, thus permitting the stent to partially or fully expand (col 3, ln 5-8)), but fails to describe a spring as the item responding to being released. However, Maass describes a self expanding stent which is released by untwisting of a coil spring (metal wire 77 is removed whereupon spring 21 is brought to expand (col 12, ln 4-6)). It would have been obvious to one skilled in the art to implement the erodable member as described by Frantzen to release the spring as described by Maass because both describe mechanisms of release for self-expanding stents.

As per claim 25, Maass describes a system wherein the spring retracts the seat upon release (In said recess spring band 21 may easily slide while stabilized at the same time, see FIG. 13b, (col 8, ln 49-51)).

Claims 1-38 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

---------- NEW CITATIONS ----------
NONE